

CLAIMS

1. A method of manufacturing a drug granule, comprising a granulation step of spraying a solution of a water soluble drug on a crystal of said water soluble drug.
- 5 2. The method of claim 1, wherein the solution of the water soluble drug is sprayed substantially without using a binder or in the absence of a binder and wherein the drug granule has a granular strength of 650-2500 gf/mm².
- 10 3. A drug granule obtained by a method comprising a granulation step of spraying a solution of a water soluble drug on a crystal of said water soluble drug.
- 15 4. The drug granule of claim 3, wherein the solution of the water soluble drug is sprayed substantially without using a binder or in the absence of a binder and wherein the drug granule has a granular strength of 650-2500 gf/mm².
- 20 5. The drug granule of claim 3 or 4, having a particle size of 0.05 mm-1.5 mm.
6. A pharmaceutical preparation comprising the drug granule of claim 3 or 4 and a pharmaceutically acceptable additive.
- 25 7. A coated granule obtained by a method comprising a step of spraying a solution of a water soluble drug on a crystal of said water soluble drug to form a drug granule, and a step of coating said drug granule with a release control film coating agent.
- 30 8. The coated granule of claim 7, wherein the drug granule has a granular strength of 650-2500 gf/mm² and is obtained by a method comprising a step of spraying the solution of the water soluble drug, substantially without using a binder or in the
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absence of a binder.

9. The coated granule of claim 7 or 8, wherein the release control film coating agent is a sustained release agent or an enteric coating agent.

10. A method of manufacturing a coated granule, which comprises:

(a) a step of spraying a solution of a water soluble drug on a crystal of said water soluble drug to form a drug granule; and
(b) a step of coating said drug granule with a release control film coating agent.

11. The method of claim 10, wherein the solution of the water soluble drug is sprayed substantially without using a binder or in the absence of a binder, and wherein the drug granule has a granular strength of 650-2500 gf/mm².

12. A granule of a water soluble drug, which is substantially free of a binder and which has a granular strength of 650-2500 gf/mm², having a crystal of said water soluble drug as a nucleus.

13. A coated granule comprising a granule of a water soluble drug, which granule comprises a crystal of said water soluble drug as a nucleus, being substantially free of a binder and having a granular strength of 650-2500 gf/mm², and a release control film coating agent coated thereon.

14. A coated granule comprising an inner layer comprising the drug granule of claim 12 and an outer layer comprising a release control film coating agent.